

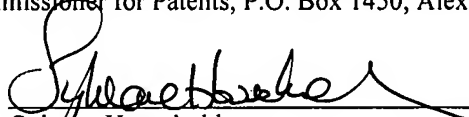
Docket No.: M0765.70052US01
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rudolph E. Tanzi et al.
Serial No.: 10/801087
Confirmation No.: 2184
Filed: March 15, 2004
For: METHODS AND COMPOSITIONS FOR DIAGNOSING,
PREVENTING, AND TREATING ALZHEIMERS DISEASE
Examiner: K. A. Ballard
Art Unit: 1649

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 7th day of August, 2007.


Sylvia Householder

Mail Stop RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The following are remarks concerning the other information cited:

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.


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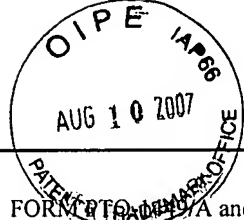
Art Unit: 1649

An early and favorable action is hereby requested.

Respectfully submitted,

By: 
John R. Van Amsterdam
Reg. No. 40,212
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: M0765.70052US01
Date: August 7, 2007
X08/07/07x



FORM PTO/DRA and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICATION NO.: 10/801087	ATTY. DOCKET NO.: M0765.70052US01	
	FILING DATE: March 15, 2004	CONFIRMATION NO.: 2184	
	APPLICANT: Rudolph E. Tanzi et al.		
	GROUP ART UNIT: 1649	EXAMINER: K.A. Ballard	
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U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

OTHER ART — NON PATENT LITERATURE DOCUMENTS

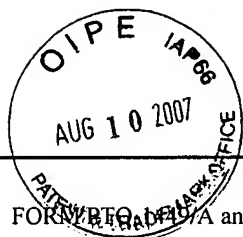
Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AGUZZI, A. et al., "Games Played by Rogue Proteins in Prion Disorders and Alzheimer's Disease," <i>Science</i> 2003; 302:814-818.	
	C2	BOUCHER, P. et al., "LRP: Role in Vascular Wall Integrity and Protection from Atherosclerosis," <i>Science</i> 2003; 300:329-332.	
	C3	CAI, H. et al., "BACE1 is the major β -secretase for generation of A β peptides by neurons," <i>Nature Neuroscience</i> March 2001; 4(3):233-234.	
	C4	DE STROOPER, B. et al., "A presenilin-1-dependent γ -secretase-like protease mediates release of Notch intracellular domain," <i>Nature</i> 1999; 398:518-522.	
	C5	DE STROOPER, B. et al., "Aph-1, Pen-2, and Nicastrin with Presenilin Generate an Active γ -Secretase Complex," <i>Neuron</i> 2003; 38:9-12.	
	C6	EDBAUER, D. et al., "Presenilin and nicastrin regulate each other and determine amyloid beta-peptide production via complex formulation," <i>PNAS</i> 2002; 99(13):8666-8671.	
	C7	GERVAIS, F.G. et al., "Involvement of Caspases in Proteolytic Cleavage of Alzheimer's Amyloid- β Precursor Protein and Amyloidogenic A β Peptide Formation," <i>Cell</i> 1999; 97:395-406.	
	C8	GRÜNINGER-LEITCH et al., "Substrate and Inhibitor Profile of BACE (β -Secretase) and Comparison with Other Mammalian Aspartic Proteases," <i>The Journal of Biological Chemistry</i> 2002; 277(7):4687-4693.	

EXAMINER:	DATE CONSIDERED:
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]



FORM PTO/A and B (modified PTO/SB/08)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheet	of	APPLICATION NO.: 10/801087	ATTY. DOCKET NO.: M0765.70052US01
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		APPLICANT: Rudolph E. Tanzi et al.	
		GROUP ART UNIT: 1649	EXAMINER: K.A. Ballard

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C9	HAASS, C. et al., "Take five-BACE and the γ -secretase quartet conduct Alzheimer's amyloid β -peptide generation," <i>The EMBO Journal</i> 2004; 23(3):483-488.	
	C10	HERREMAN, A. et al., " γ -Secretase activity requires the presenilin-dependent trafficking of nicastrin through the Golgi apparatus but not its complex glycosylation," <i>Journal of Cell Science</i> 2003; 116(6):1127-1136.	
	C11	IKEUCHI, T. et al., "The Notch Ligands, Delta1 and Jagged2, Are Substrates for Presenilin-dependent ' γ -Secretase' Cleavage," <i>The Journal of Biological Chemistry</i> 2003; 278(10):7751-7754.	
	C12	KANG, D.E. et al., "Presenilin Couples the Paired Phosphorylation of β -Catenin Independent of Axin: Implications for β -Catenin Activation in Tumorigenesis," <i>Cell</i> 2002; 110:751-762.	
	C13	KIM, T. et al., "Alternative Cleavage of Alzheimer-Associated Presenilins During Apoptosis by a Caspase-3 Family Protease," <i>Science</i> 1997; 277:373-376.	
	C14	KITAZUME, S. et al., "Alzheimer's beta -secretase, beta -site amyloid precursor protein-cleaving enzyme, is responsible for cleavage secretion of Golgi-resident sialyltransferase," <i>PNAS</i> 2001; 98(24):13554-13559.	
	C15	MARAMBAUD, P. et al., "A presenilin-1/ γ -secretase cleavage releases the E-cadherin intracellular domain and regulates disassembly of adherens junctions," <i>The EMBO Journal</i> 2002; 21(8):1948-1956.	
	C16	MURPHY, M.P. et al., "Overexpression of nicastrin increases A β production," <i>The FASEB Journal</i> 2003; 17:1138-40.	
	C17	PUGLIELLI, L. et al., "Ceramide Stabilizes β -Site Amyloid Precursor Protein-cleaving Enzyme 1 and Promotes Amyloid β -Peptide Biogenesis," <i>The Journal of Biological Chemistry</i> 2003; 278(22):19777-19783.	
	C18	SATO, N. et al., "Upregulation of BiP and CHOP by the unfolded-protein response is independent of presenilin expression," <i>Nature Cell Biology</i> 2002; 2:863-870.	
	C19	SELKOE, D. et al., "Notch and Presenilin: Regulated Intramembrane Proteolysis Links Development and Degeneration," <i>Annu. Rev. Neurosci.</i> 2003; 26:565-97.	
	C20	STEINHUSEN, U. et al., "Cleavage and Shedding of E-cadherin after Induction of Apoptosis," <i>The Journal of Biological Chemistry</i> 2001; 276(7):4972-4980.	
	C21	STRUHL, G. et al., "Presenilin is required for activity and nuclear access of Notch in <i>Drosophila</i> ," <i>Nature</i> 1999; 398:522-525.	

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	C22	TESCO, G. et al., "Caspase Activation Increases β -Amyloid Generation Independently of Caspase Cleavage of the β -Amyloid Precursor Protein (APP)," <i>The Journal of Biological Chemistry</i> 2003; 278(46):46074-46080.	
	C23	VASSAR, R. et al., " β -Secretase Cleavage of Alzheimer's Amyloid Precursor Protein by the Transmembrane Aspartic Protease BACE," <i>Science</i> 1999; 286:735-741.	
	C24	WOLFE, M.S. et al., "Two transmembrane aspartates in presenilin-1 required for presenilin endoproteolysis and γ -secretase activity," <i>Nature</i> 1999; 398:513-517.	
	C25	YUAN, J. et al., "Apoptosis in the nervous system," <i>Nature</i> 2000; 407: 802-809.	

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